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REMARKS

Claims 1-10, 12-15, and 21-33 are pending in this application. Claims 1 and 2 have been amended. Support for the amendment is found in the specification and claims as filed.

Claim Rejection - 35 U.S.C. § 102(b) - Ito

Claims 1, 2, 21, and 24-29 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. 5,384,028 ("Ito"). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994). Ito does not disclose every element of Applicants' claims, and therefore cannot be considered an anticipating reference under 35 U.S.C. § 102(b).

Applicants' pending independent Claim 1 recites a sensor head comprising, *inter alia*, "a non-conductive body configured for implantation in a host." Claim 2 further recites subcutaneous implantation. Ito is directed to a biosensor for *ex vivo* use. The biosensor of Ito is not configured for implantation into a host. Thus, Ito does not disclose a sensor head "configured for ... implantation," and therefore cannot anticipate Claims 1, 2, 21, and 24-29. Applicants therefore respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) -Heller et al. in view of Shults et al. and Nagata et al.

Claims 1, 2, 5-10, 12-15, and 22-33 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. 6,392,161 ("Heller et al.") in view of U.S. 6,001,067 ("Shults et al.") and U.S. 4,871,440 ("Nagata et al."). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). There is no such suggestion or teaching, and, in fact, the disclosures teach away from the invention as recited in the pending independent claims. A *prima facie* case of obviousness cannot be established if the disclosure of the cited prior art, when taken as a whole, teaches away from the claimed invention. *See, e.g., M.P.E.P.* § 2141.02.

The Office Action asserts that it would have been obvious to modify Heller et al. to use the electrode structure of Shults et al., as it is merely the substitution of one known equivalent structure for another. Applicants respectfully disagree. Heller et al. disclose a "*small* (e.g., 0.29

mm), recessed, non-corroding metal (e.g., gold, platinum, palladium) or carbon wire electrode for subcutaneous in vivo glucose monitoring” (col. 2, lines 58-60) (*emphasis added*). Heller et al. are concerned particularly with the size of the device and prefer its size to be that as stated at col. 4, line 23: “the outside diameter *a* of the wire is preferably about 0.25 mm or less, and *the outside diameter b of the insulated wire is preferably about 0.3 mm or less*” (*emphasis added*). Additionally, Example 2 at column 13 discloses the insertion of the sensor “using a 22 gauge Per-Q-Cath Introducer (Gesco International, San Antonio, Tex.) on the rat's thorax, or subcutaneously in the intrascepal area through a small surgical incision” (see also claims 25 and 31, *emphasis added*). Thus, the glucose sensor of Heller et al. is specifically configured for transcutaneous implantation via an introducer such as a needle (*i.e.*, 22 gauge) and the body of the device (*e.g.*, the portion housing the electronics, etc.) is located outside of the body.

In contrast, Shults et al. is directed to a wholly implantable glucose sensor wherein the electrode and membrane structure are integrally formed on the body that is adapted to be wholly implanted into a host for long term glucose sensing. Specifically, in contrast to Heller et al., considerations of electrode size and method of insertion of the electrodes are not a concern in sensor configuration. The sensor of Shults et al., which includes “a non-conductive body, a working electrode, a reference electrode, and a counter electrode, wherein the electrodes pass through the non-conductive body forming an electrochemically reactive surface at one location on the body and an electronic connection at another location on the body” cannot be merely substituted into the glucose sensor of Heller et al., because the electrode structure of Shults et al. would not yield a glucose sensor that could be implanted using a 22 gauge introducer due to its size, and the structure of Shults et al. would not produce a transcutaneous glucose sensor wherein the sensor electrodes are implanted and the housing and electronics are outside the body. Therefore, the substitution of the structure of the Shults et al. glucose sensor into the Heller et al. glucose sensor would produce a sensor unsuitable for its intended use, namely a transcutaneous sensor wherein the sensor electrodes are inserted into a host via an introducer needle and wherein the electronics remain outside the body (also known as a “needle sensor” in the art). Accordingly, there is no motivation to combine.

The teachings of Nagata et al. do not overcome the deficiencies of Heller et al. and Shults et al., and in fact, the disclosure teaches away from such a combination. Specifically, the glucose sensing method used by Heller et al. is not concerned with improving oxygen availability. In

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fact, oxygen needs to be limited in the membrane system of the Heller et al. device in order to achieve acceptable function. The larger counter electrode of Nagata et al. increases the oxygen available to the electrodes. Accordingly, combining the electrode system of Nagata et al. with the device of Heller et al. would result in poorer performance of the “wired enzyme” technology sensor of Heller et al. rather than improved performance. Thus there is no motivation to combine.

Accordingly, there is no teaching or motivation to combine or modify the teachings of the cited references in such a way as to yield the sensor as presently claimed. A *prima facie* case of obviousness therefore cannot be made, and Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) - Shults et al. in view of Ito

Claims 1, 2, 5-10, 12-15, and 22-33 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shults et al. in view of Ito. There is no suggestion or motivation to combine the teachings of Shults et al. and Ito to yield the sensor as presently claimed.

As discussed above, Shults et al. is directed to a wholly implantable glucose sensor for glucose sensing in subcutaneous tissue *in vivo*, while Ito is directed to a sensor for *ex vivo* use. The Office Action asserts that it would have been obvious to substitute the configuration of electrodes taught by Ito for the configuration of electrodes disclosed by Shults et al. to yield the sensor as claimed. Applicants respectfully disagree. The electrodes of Shults et al. are formed from bulk metal wires that extend through a non-conductive body to connect an electrochemically reactive surface on one side of the body to an electronic connection on the other side of the body. The electrodes of Ito, in contrast, are deposited on a substrate and do not extend therethrough. If one were to merely substitute the electrode structure taught by Ito into the electrode structure disclosed by Shults et al., the electrodes would not extend through the body of the device, as required in the Shults et al. device. If, on the other hand, one were to attempt to produce bulk metal wires that would result in a configuration resembling that of Ito (Fig. 2), customized and expensive manufacturing processes would be required. Wires with a cross-sectional shaping of the electrodes illustrated in Fig. 2 of Ito are not generally available and one of ordinary skill in the art would not be motivated to manufacture or utilize wires of such configuration. Additionally, the amount of pure metal that would be required to create such an electrode structure would be extremely expensive (*i.e.*, the price of an ounce of platinum was

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\$878 as of March 18, 2005). Accordingly, modification of the teachings of the cited reference to yield an electrode system as presently claimed would be neither feasible for a marketable product nor obvious to one of ordinary skill in the art.

Moreover, the mere substitution of an electrode structure of an implantable long term continuous glucose sensor with an electrode structure from a test strip that measures a single glucose value for a single blood sample would not be obvious due to the differing design and manufacturing considerations for implantable sensors versus test strips. For example, a marketable test strip must be designed to use relatively cheap materials (as they are disposable and are not reusable for more than one blood sample), which is why electrodes in test strips are generally formed by deposition of electrode material, rather than the use of bulk metals. In contrast, a continuous long term implantable sensor is designed to be robust with the electrode able to handle long term and regular use, thus bulk metals provide the necessary stability for such usages. Accordingly, when viewed as a whole, there is no suggestion to combine or modify the teachings of the cited references to yield the sensor as presently claimed.

Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) –Heller et al. in view of Shults et al., Nagata et al., and Schulman et al.

Claims 3 and 4 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. 6,392,161 (“Heller et al.”) in view of U.S. 6,001,067 (“Shults et al.”) and U.S. 4,871,440 (“Nagata et al.”), in further view of U.S. 6,119,028 (“Schulman et al.”). As discussed above, pending independent Claims 1 and 2, from which Claims 3 and 4, respectively, depend, are not obvious over Heller et al. in view of Shults et al. and Nagata et al. Schulman et al., which teaches a silicone membrane, does not overcome the deficiencies of Heller et al., Shults et al., and Nagata et al. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) - Shults et al. in view of Ito and Schulman et al.

Claims 3 and 4 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shults et al. in view of Ito, in further view of Schulman et al. As discussed above, pending independent Claims 1 and 2, from which Claims 3 and 4, respectively, depend, are not obvious over Shults et al. in view of Ito. Schulman et al., which teaches a silicone membrane, does not overcome the deficiencies of Shults et al. and Ito. Accordingly, Applicants respectfully request withdrawal of the rejection.

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Claim Rejection - 35 U.S.C. § 103(a) – Heller et al. in view of Shults et al., Nagata et al., and Ward et al.

Claim 21 has been rejected under 35 U.S.C. §103(a) as obvious over Heller et al. Shults et al. and Nagata et al., in further view of U.S. 6,119,028 (“Ward et al.”). As discussed above, pending independent Claim 2, from which Claim 21 depends, is not obvious over Heller et al. in view of Shults et al. and Nagata et al. Ward et al., which teaches a ceramic housing, does not overcome the deficiencies of Heller et al., Shults et al., and Nagata et al. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) – Shults et al. and Ito in view of Ward et al.

Claim 21 has been rejected under 35 U.S.C. §103(a) as obvious over Shults et al. and Ito, in further view of U.S. 6,119,028 (“Ward et al.”). As discussed above, pending independent Claim 2, from which Claim 21 depends, is not obvious over Shults et al. and Ito. Ward et al., which teaches a ceramic housing, does not overcome the deficiencies of Shults et al. and Ito. Accordingly, Applicants respectfully request withdrawal of the rejection.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,

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